

REMARKS

As a preliminary matter, the undersigned thanks the Examiner for the courtesy of the in-person interview conducted on 10/23/2007. The undersigned respectfully reminds the Examiner of the offer that was made to contact the undersigned to address any question or concerns that the Examiner may have prior to generation of the next Action on the merits. Given the age of this Application, Applicants sincerely appreciate all efforts that the Examiner can make to expedite prosecution of this case.

As stated during the in-person interview, Applicants believe the currently amended claims to be allowable over the art of record.

SUPPORT FOR CLAIMS:

35 USC § 112:

Amendments to claims **48** and **61** are supported by the written description and claims **1** and **22** as originally filed.

Support for the amendment to claims **48, 49, 53, 61**, and **66** can be found on pages 10, 11, 14, and 15 of the application as filed. In claim **48**, “jojoba-derived material” is described on page 14, lines 8-16 of the application as filed. A description of “providing substantive benefits to the skin of an animal subject” is found on page 14, lines 20-23 of the application as filed. A description of “10% - 55% (wt./wt.) non-polar unsaponifiable fraction and a 45% - 90% (wt./wt.) polar hydrophilic salt fraction” is found on page 10, lines 12-18 of the application as filed. Further, “the tandem reaction products of saponification of jojoba oil starting material” is detailed on page 15, lines 20-29 and page 16, lines 1-23 of the application as filed. In claims **48-49** and **62**, a “jojoba oil starting material having about 45% unsaponifiables (wt./wt. of jojoba oil) prior to saponification” is indicated in the table on page 11. In claims **53** and **66**, the limitation “wherein said composition comprises an ingredient in at least one of: emollients, conditioners, pigments, dyes, pharmaceuticals, ultraviolet radiation absorbers, physical radiation blocks, insect repellents, animal repellents, insecticides, pesticides, herbicides, animal attractants, fragrances, and hormones”, is described on page 14, line 24- page 15 line 3 of the application as filed. In claim **61**, a description of jojoba oil starting material with “about 45% (wt./wt.) of long chain carbon material that varies between 18 and 24 carbons in length prior to saponification,” can be found on page 14, lines 8-13 of the application as filed. Accordingly, no new matter has therefore been introduced.

The Examiner indicates that “a straightforward reading leads one to believe there is 10-55% unsaponifiables, but there is not; the specification states 6% only of unsaponifiables renders the term unsaponifiables valid. So what does 10-55% mean? 55% thus has only to require 6% to be unsaponifiable.” Page 10, line 13, of the application as filed, discloses the term “unsaponifiables” to include “compositions that comprise *at least* 6% by weight of total organic materials that are unsaponifiable and at least 10% by weight of organic materials that are saponifiable [...] includ[ing] compositions containing from 6-90% by weight of organics of unsaponifiable materials”. (emphasis added). Additionally, jojoba oil is described as having an unsaponifiable fraction corresponding to about 45% in the table at page 11 of the application as filed. Thus, the application as filed indicates that there are *at least* 6% unsaponifiables, which is not violated by a designation of 10% - 55% unsaponifiables in the claims. (emphasis added).

The Examiner indicates that “[i]mportantly, it is not stated what the 10-55% is a % of. The basis is absent. Neither can we determine the basis of the 45-90%, or the 45% of the jojoba oil.” The Examiner further indicates that “the 10-55% and 45-90% are not stated to be of jojoba oil; they corresponds or [sic] saponification products of jojoba oil. It is unclear what % of the composition is jojoba oil, and what % is other oils [sic] or fats. If jojoba oil is the portion of the composition that is 10-55% non-polar and 45-90% polar (claim 48) then that should be stated; as should the basis-the total composition; the unsaponifiables, the jojoba oil or what, and by volume, weight or ?”

Applicants respectfully submit that the language of: “said composition having 10% - 55% (wt./wt.) non-polar unsaponifiable fraction and a 45% - 90% (wt./wt.) polar hydrophilic salt fraction, wherein said non-polar unsaponifiable fraction and said polar hydrophilic salt fraction total 100% of said jojoba-derived material, wherein said jojoba-derived material corresponds to the tandem reaction products of saponification of jojoba oil starting material” as required by claims **48** and **61**, as amended, and wherein said jojoba oil starting material has “about 45% unsaponifiable material (wt./wt. of total jojoba oil) prior to saponification” (as required by claim **48**, as amended) and/or “comprises about 45% (wt./wt.) of long chain carbon material that varies between 18 and 24 carbons in length prior to saponification” (as required by claim **61**, as amended) obviate the Examiner’s concerns.

Additionally, the Examiner states that “[a]lthough patentable weight over the prior art might not be afforded. A product by process rendering of claims 48 and 61 might provide some clarity now lacking. In particular, insert “that” after saponification at line 4 of claim 48, and put back the deleted material

following lines 4 and 5, and then delete “in situ”.” Applicants respectfully submit that claims **48** and **61**, as amended, provide sufficient clarity and should be allowed in their current form.

The Examiner indicates that “[t]he problem of the composition comprising 10-55% unsaponifiables would remain however. Is the 55% really only required to be 6% or is it 55%?” Applicants are affirmatively unaware as to exactly what the Examiner is referring to with regard to “the 55% really only required to be 6% or is it 55%”. That notwithstanding, Applicants submit that claims **48** and **61** have been amended to further clarify that the composition has “10% - 55% (wt./wt.) non-polar unsaponifiable fraction and a 45% - 90% (wt./wt.) polar hydrophilic salt fraction, wherein said non-polar unsaponifiable fraction and said polar hydrophilic salt fraction total 100% of said jojoba-derived material”. Applicants respectfully submit that claims **48** and **61**, as amended, should obviate the Examiner’s concerns.

Further, the Examiner indicates that the “long chain” should be quantified” in claim **61**. Applicants respectfully submit that claim **61**, as amended, limit “long chain material” to material “that varies between 18 and 24 carbons in length prior to saponification.” Page 14, lines 12 -13, of the application as filed, supports this description of “long chain”. Accordingly, no new matter has been introduced in this regard.

In view of Applicants’ instant amendments, the Examiner’s objections with respect to 35 U.S.C. §112 have been obviated. Accordingly, Applicants respectfully request that these rejections be withdrawn.

35 USC § 102(b):

Claims **48, 49, 53, 57, 61, 62, 66**, and **70 – 72** stand rejected under 35 U.S.C. § 102(b) as being anticipated by Koulbanis *et al.* (US 4,324,802). Applicants respectfully traverse this rejection.

To support a rejection as being anticipated under §102, a single reference must disclose each and every element and limitation of the claims. In the absence of even a single claim element or limitation, a rejection under §102 is inappropriate. Further, it is well established that the terms of a claim are generally given their ordinary and customary meaning as they would have to a person of ordinary skill in the art. The person of ordinary skill in the art is deemed, however, to have read and understood the claims in the context of the specification.

As a preliminary matter, Applicants are affirmatively unaware as to the meaning of the Examiner's statement, presumably in regard to Koulbanis *et al.*, that "[n]ew claims are re-written and rejected, previously presented claims. The instant claim language is not seen to preclude other saponification products than those from jojoba oil." Does the Examiner intend to suggest that Koulbanis *et al.* anticipates the present invention because the claim language did not preclude saponification products of oils other than jojoba oil? Applicants respectfully request clarification as to what the Examiner intends to communicate so that the record of prosecution may be rendered clear for potential Appeal.

That notwithstanding, Koulbanis *et al.* fails to anticipate each and every limitation of claims **48** and **61**, as amended, in that Koulbanis *et al.* does not teach "a composition comprising jojoba-derived material for providing substantive benefits to the skin of an animal subject, said composition having 10% - 55% (wt./wt.) non-polar unsaponifiable fraction and a 45% - 90% (wt./wt.) polar hydrophilic salt fraction, wherein said non-polar unsaponifiable fraction and said polar hydrophilic salt fraction total 100% of said jojoba-derived material, and wherein said jojoba-derived material corresponds to the tandem reaction products of saponification of jojoba oil starting material" as required by claims **48** and **61**, as amended, and wherein said jojoba oil starting material has "about 45% unsaponifiable material (wt./wt. of total jojoba oil) prior to saponification" (as required by claim **48**, as amended) and/or "comprises about 45% (wt./wt.) of long chain carbon material that varies between 18 and 24 carbons in length prior to saponification" (as required by claim **61**, as amended).

Specifically, Koulbanis *et al.* does not teach the use of tandem reaction products of saponification of jojoba oil starting material, as required by claims **48** and **61**, as amended. In fact, Koulbanis teaches the use of a cosmetic oil that "contains a mixture of at least two vegetable oils...and at least one *previously extracted* non-saponifiable fraction." col. 2, lines 14-18. Moreover, the previously extracted non-saponifiable fractions that are subsequently added to a cosmetic oil in Koulbanis *et al.* do not include non-saponifiable fractions of jojoba oil. *See* col. 2, lines 18-24 ("non-saponifiable fractions include principally, the non-saponifiable fractions of soybean, avocado, corn and turnsole oil, and at least one previously extracted non-saponifiable fraction").

Consequently, the Examiner's later assertion that "jojoba oil is present in [...] Koulbanis and so would meet the instant descriptive components of jojoba oil prior to saponification" is equally irrelevant, as Koulbanis *et al.* does not teach saponification of jojoba oil, let alone use of the tandem reaction products of saponification of jojoba oil starting material, as required by claims **48** and **61**, as amended.

Further, Koulbanis *et al.* does not teach the use of polar hydrophilic salts *at all*, let alone use of polar hydrophilic salts as a tandem reaction product of saponification of jojoba oil, as required by claims **48** and **61**, as amended.

Inasmuch as claims **49**, **53**, **57-59** and **62**, **66**, **70-72**, as amended, respectively depend from, further limit and incorporate all of the elements of claims **48** and **61**, as amended, these claims are also allowable over the cited art. Applicants therefore submit that claims **48-49**, **53**, **57-59** and **61-62**, **66**, **70-72** are allowable in view of Koulbanis *et al.* and respectfully request Examiner to withdraw the § 102(b) rejections of the same.

Claims **61**- **62**, **66**, and **70-72** stand rejected under 35 U.S.C. § 102(b) as being anticipated by Moy (US 5,928,659). Applicants respectfully traverse this rejection.

As a preliminary matter, Applicants are affirmatively unaware as to the meaning of the Examiner's statement, presumably in regard to Moy, that “[n]ew claims are re-written and rejected, previously presented claims. Jojoba oil is present, thus, would have 45% long chain carbon. The tandem reaction products, as applied to avocado oil, also correspond to the products one would obtain from other oils, inclusive of jojoba.” Does the Examiner intend to suggest that Moy anticipates the present invention because it teaches jojoba oil and saponification of avocado oil? Applicants respectfully request clarification as to what the Examiner intends to communicate so that the record of prosecution may be rendered clear for potential Appeal.

That notwithstanding, Moy fails to anticipate each and every limitation of claim **61**, as amended, in that Moy does not teach “a composition comprising jojoba-derived material for providing substantive benefits to the skin of an animal subject, said composition having 10% - 55% (wt./wt.) non-polar unsaponifiable fraction and a 45% - 90% (wt./wt.) polar hydrophilic salts fraction, wherein said non-polar unsaponifiable fraction and said polar hydrophilic salt fraction total 100% of said jojoba-derived material, and wherein said jojoba-derived material corresponds to the tandem reaction products of saponification of jojoba oil starting material having about 45% (wt./wt. of jojoba oil) of long chain carbon material that varies between 18 and 24 carbons in length prior to saponification”, as required by claim **61**, as amended.

Moy teaches use of formulations including purified avocado oil unsaponifiables in combination with various oils, fatty acids for the treatment of stretch marks and keratoses. col. 2, lines 63-67. By contrast, Moy does not teach the use of tandem reaction products of the saponification of jojoba oil starting material, as required by claim **61**, as amended, of the present invention. In fact, Moy teaches that “UFA [unsaponifiable fraction of avocado oil] can be prepared by using conventional methods of saponification

to **remove** saponifiable lipids from organic solvent (*i.e.*, hexane) extracts of avocado seeds.” col. 4, lines 25-27 (emphasis added). Thus, Moy teaches saponification of avocado oil, **removal** of saponifiable fractions of avocado, **extraction** of the unsaponifiable fraction of avocado oil and subsequent addition of the unsaponifiable fraction to various oils for treating stretch marks and keratoses. This teaching is inapposite to the present invention, which specifically teaches use of the tandem reaction products of jojoba oil starting material. In other words, the present invention **does not teach** the removal of avocado oil saponifiables, extraction and/or subsequent addition of externally derived unsaponifiables of avocado oil to other oils, as disclosed in Moy.

The Examiner’s assertion in regard to “jojoba oil is present, thus would have 45% long chain carbon” is ambiguous, and clarification is required in order to render the record of prosecution clear on potential Appeal. Regardless of what the Examiner intends to communicate with regard to jojoba oil, Moy does not teach use of tandem reaction products of the saponification of jojoba oil starting material, as required by claim **61**, as amended. In fact, Moy **does not teach** the saponification of jojoba oil *at all*. Consequently, the Examiner’s later assertion that “jojoba oil is present in Moy [...] and so would meet the instant descriptive components of jojoba oil prior to saponification” is equally irrelevant, as Moy does not teach saponification of jojoba oil, let alone use of the tandem reaction products of saponification of jojoba oil starting material, as required by claim **61**, as amended. Rather, Moy teaches use of unsaponifiables of avocado oil extracted from seeds through a press process and/or saponification, and subsequently added to a mixture of oils (which in some embodiments includes small amounts of jojoba oil), for the treatment of stretch marks and keratoses. *See, e.g.*, col.4, lines 25-35 and Examples 3 and 4. This is wholly different from the present invention.

Inasmuch as claims **62**, **66**, and **70-72**, as amended, depend from, further limit and incorporate all of the elements of claim **61**, as amended, these claims are also allowable over the cited art. Applicants therefore submit that claims **61-62**, **66**, and **70-72** are allowable in view of Moy and respectfully request Examiner to withdraw the § 102(b) rejections of the same.

Claims **48-49**, **53**, **61-62**, and **66** stand rejected under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a), as obvious over Wells (US 2,450,403). The Examiner has utilized the conjunction “or” in the construction of the basis/bases for rejection. Accordingly, the rejection is not clear and does not particularly point out the basis/bases for rejection. Applicants are unable to determine if the Examiner proposes that Wells is intended to be applied in view of the novelty requirements of 35 U.S.C. § 102(b), the non-obviousness requirements of 35 U.S.C. § 103(a), or both. One possible interpretation of the rejection (at least as it currently reads) is that the Examiner considers the rejection

under 35 U.S.C. § 102(b) to be of such insubstantial weight as to warrant the fall-back position that it probably meets the criteria for establishing a *prima facie* case for obviousness under 35 U.S.C. § 103(a). Applicants respectfully request clarification on this point so that the record of prosecution is rendered clear on potential Appeal.

Applicants respectfully request clarification as to what the Examiner intends to convey by the following: “Jojoba oil, thus meeting the criteria of the instant claims, is heated and saponified with sulfur, and so would result in a composition, suitable to provide substantive benefits upon application to the skin, if one so wished, having 10-55% non-polar unsaponifiables and 49-50% polar hydrophilic salts. Added emollients include mineral oil (column 6, example 8).” Does the Examiner suggest that, with respect to “jojoba oil, thus meeting the criteria of the instant claims”, Applicants are claiming jojoba oil? As evidenced by claim **48** and **61**, as amended, this is clearly not the case.

In regard to the Examiner’s §102(b) rejection, Wells fails to anticipate each and every limitation of claims **48** and **61**, as amended, in that Wells fails to teach “a composition comprising jojoba-derived material for providing substantive benefits to the skin of an animal subject, said composition having 10% - 55% (wt./wt.) non-polar unsaponifiable fraction and a 45% - 90% (wt./wt.) polar hydrophilic salt fraction, wherein said non-polar unsaponifiable fraction and said polar hydrophilic salt fraction total 100% of said jojoba-derived material, and wherein said jojoba-derived material corresponds to the tandem reaction products of saponification of jojoba oil starting material” as required by claims **48** and **61**, as amended, and wherein said jojoba oil starting material has “about 45% unsaponifiable material (wt./wt. of total jojoba oil) prior to saponification” (as required by claim **48**, as amended) and/or “comprises about 45% (wt./wt.) of long chain carbon material that varies between 18 and 24 carbons in length prior to saponification” (as required by claim **61**, as amended).

First, Wells does not teach anything related to “tandem reaction products of saponification of jojoba oil starting material” as indicated in claims **48** and **61**, as amended. Rather, Wells teaches the sulfurization of jojoba oil by heating the oil in presence of sulfur. *See* col. 3, lines 62-66. This teaching is wholly inapplicable to the claimed invention. The processes of sulfurization and saponification are two different chemical processes producing separate and distinct reaction products. Sulfurization, unlike saponification, produces a plasticized material. Upon sulfurization, the wax esters of jojoba oil are crosslinked whereas the wax esters of jojoba oil are hydrolyzed in the saponification process. Thus, no fatty alcohols are produced in the process of sulfurization as would be produced by saponification.

Further, sulfurized jojoba oil according to Wells is not appropriate for use on the “skin of an animal subject”, as indicated in claims **48** and **61**, as amended, in that it has a foul odor and has no emollient or substantive properties. Rather, sulfurized jojoba oil disclosed in Wells is for use in industrial lubricants such as for machine parts, transmission fluids (col. 6, lines 51-53), industrial high temperature processes (col. 7, lines 1-2), or as an additive for extreme pressure systems (col. 1, lines 6-9) as a more efficient alternative to sperm oil. *See, e.g.*, col.6, lines 9-19. These applications are inapposite to the teaching of the present invention, which requires use of tandem reaction products of saponification of jojoba oil starting material to provide substantive benefits to the skin of an animal subject. As Wells does not teach saponification of jojoba oil at all, let alone use of tandem reaction products of saponification for substantive benefits to the skin, Wells cannot be viewed to anticipate claims **48** and **61**, as amended.

Inasmuch as claims **49**, **53**, **57-59** and **62**, **66**, **70-72**, as amended, respectively depend from, further limit and incorporate all of the elements of claims **48** and **61**, as amended, these claims are also allowable over the cited art. Applicants therefore submit that claims **48-49**, **53**, **57-59** and **61-62**, **66**, **70-72** are allowable in view of Wells and respectfully request Examiner to withdraw the § 102(b) rejections of the same.

35 USC § 103(a):

Claims **48-49**, **53**, **61-62**, and **66** are rejected under 35 U.S.C. § 103(a) as being purportedly obvious over Wells *et al.* (US 2,450,403). Applicants respectfully traverse this rejection. Applicants further submit that a *prima facie* case of obviousness has not been established.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art. MPEP § 2143.01. Second, there must be a reasonable expectation of success to modify or combine the cited references to achieve the claimed invention. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *See* MPEP 2143. Additionally, the teaching or suggestion to make the claimed combination and the reasonable expectation of success cannot be based solely on Applicants' disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); *See also* Memorandum of 03 May 2007 from Margaret A. Focarino to USPTO Technology Center Directors regarding Supreme Court decision on *KSR Int'l. Co. v. Teleflex, Inc.* 127 S.Ct. 1727 (2000).

Following the Supreme Court's *KSR* decision, a number of precedential opinions by Board of Patent Appeals and Interferences (BPAI), as well as revised Examination Guidelines published by the United States Patent Office, have set out a slightly different legal standard for obviousness than that stated in the current version of the MPEP. Specifically, combining the prior art elements according to their established functions to produce the claimed invention may not have been viewed as predictable. *See Ex parte Mary Smith*, Appeal 2007-1925, Application No. 09/391,869, decided 25 June 2007; *Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc.* 127 S.Ct. 1727 (2007).

Applicants submit that Wells does not teach or suggest "a composition comprising jojoba-derived material for providing substantive benefits to the skin of an animal subject" including "tandem reaction products of a jojoba oil starting material" as set forth in Applicants' claims **48** and **61**, as amended. In fact, Wells teaches away from the present invention by teaching a different chemical process for a wholly different purpose. Specifically, Wells teaches sulfurization of jojoba oil for industrial uses, such as uses for lubrication under extreme pressure conditions. *See* col. 1, lines 6-9, col. 6, lines 51-53, col. 7, lines 1-2. Sulfurized jojoba oil is foul smelling and produces a plasticized material. By contrast, the present invention teaches the use of tandem reaction products of saponification of jojoba oil starting material to provide substantive benefits to the skin.

Applicants further submit that there is no motivation or suggestion to be found in the Wells reference, nor in the knowledge generally available to one of ordinary skill in the art, to modify Well or to combine Well with any other reference to practice the invention of Applicants' claims **48** and **61**, as amended.

It is important to note that the Examiner has failed to disclose a combination of Wells with any reference or teaching of record and/or any teaching of knowledge generally available to one of ordinary skill in the art. Accordingly, there can be no motivation or suggestion to combine when a combination is not even proposed. Applicant's respectfully request clarification on this point so that Applicants are not forced to perform guesswork to determine how the Examiner has formulated the rejection under 35 U.S.C. § 103(a).

Moreover, under the slightly revised legal standard in view of the Supreme Court's decision in *KSR*, any combination of prior art elements according to establish the claimed invention may not have been viewed as predictable where such a combination is not even proposed.

Additionally, because there is no motivation or suggestion to combine Wells with any other reference to practice the invention of claims **48** and **61**, as amended, there can be no reasonable expectation of success.

“With respect to core factual findings in a determination of patentability, [the Examiner] cannot simply reach conclusions based on [his/her] own understanding or experience – or on [his/her] assessment of what would be basic knowledge or common sense. Rather [the Examiner] must point to some concrete evidence in the record in support of these findings.” *In Re Zurko*, 258 F.3d 1379 (2001).

Moreover, Applicants submit that, in view of the shortcomings of the cited reference, the Examiner’s conclusions can only be reached through the impermissible use of hindsight. The Examiner provides no objective reason to combine the teachings of Wells with any other reference to arrive at the claimed invention. “A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning.” *KSR* at 1742.

Inasmuch as claims **49**, **53**, **57-59** and **62**, **66**, **70-72**, as amended, respectively depend from, further limit and incorporate all of the elements of claims **48** and **61**, as amended, these claims are also allowable over the cited art. Applicants therefore submit that claims **48-49**, **53**, **57-59** and **61-62**, **66**, **70-72** are allowable in view of Wells and respectfully request Examiner to withdraw the § 103(a) rejections of the same.

CONCLUSION

Claims **48**, **49**, **53**, **57**, **61**, **62**, **66**, and **70 – 72**, as amended, are pending in the application. Consideration and allowance of all pending claims **48**, **49**, **53**, **57**, **61**, **62**, **66**, and **70 – 72** as amended, is earnestly requested.

Respectfully submitted,
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